K083221

SUMMARY AND CERTIFICATION

FEB - 3 2009

510(k) SUMMARY

Summary of Safety and Effectiveness

In accordance with 21 CFR 807.92, the following information constitutes the Aidera summary for the ***Diasend System.***

SUBMITTER'S NAME:	Aidera
ADDRESS:	Aidera AB Sahlgrenska Science Park Medicinaregatan 8A SE 413 46 Goteborg Sweden
CONTACT PERSON:	Anders Sonesson
TELEPHONE NUMBER:	+46 31 741 17 85
FAX NUMBER:	+46 31 741 17 01
DATE OF SUBMISSION:	October 30, 2008

1. Identification of device

Proprietary Name:	Diasend
Common Name:	Radiofrequency physiological signal transmitter and receiver
Classification Status:	Class II according to Sec. 880.2910 and 862.1345
Product Codes:	MRZ and NBW

2. Equivalent devices

K063484, Intermed Advicor Inc, Patient Data Handler & Devices
K072698, Confidant Inc. Confidant 2.5
K042768, iMetrikus Inc. MediCompass Connect

3. Description of the Device

Diasend is a system for transmitting of data from patients home monitoring devices and consists of a transmitter, a server database and a website available for the care provider and the patient.

4. Intended use

Diasend is intended for storage and transmitting data from home monitoring devices such as glucose meters and insulin pumps to a server database.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Anders Sonesson
Chief Executive Officer
Aidera AB
Sahlgrenska Science Park
Medicinaregatan 8A
SE 413 46 Goteborg
SWEDEN

FEB - 3 2009

Re: K083221
Trade/Device Name: Aidera Diasend System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: MRZ, NBW
Dated: December 23, 2009
Received: December 30, 2009

Dear Mr. Sonesson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K083221

Device Name:

Aidera Diasend System

Indications For Use:

Diasend is intended for transmitting data from home monitoring devices such as glucose meters and insulin pumps to a server data base.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K083221